The Unitized Patient Isolator: a Microbiological Demonstration of Its Reliability

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THE USE of individual or self-contained isolation units as a means of direct or reverse patient isolation has its origin in the study of gnotobiotics. Engineering advances in germfree animal technology, particularly the development of flexible plastic isolators, have now made it possible to prevent the colonization of the susceptible host or patient by exogenous microorganisms.

The basic functions of the germfree animal and patient isolators are identical; however, their design requirements are entirely different. Successful operation of a germfree isolator is totally dependent upon the erection and maintenance of a microbiologically impregnable barrier. Provision for absolute protection against the introduction of viable microorganisms, however, imposes limitations upon access to the interior of the isolator. While limited access may not interfere with the maintenance of an animal in isolation, it becomes a critical factor in the treatment of a human patient in isolation. Therefore, the primary design requirement for a patient isolator is that the protective barrier which is erected between the patient and the external environment may not interfere in any way with standard medical and nursing care procedures. This report summarizes the results obtained from a series of microbiological evaluations of a patient isolation unit designed to fulfill this requirement.

The Patient Isolator System

The isolator discussed in this report is the Mark V model of the "Life Island Isolation System"† (Fig. 1). It is one of several similar units placed by the USAMRDC both at the Walter Reed Army Institute of Research and elsewhere for evaluation. The isolator, together with an appraisal of the nursing care requirements essential for its full utilization, have been described elsewhere.[1,2]

The actual isolation enclosure is formed by two flexible polyvinyl-chloride plastic (PVC) bags which surround a standard hospital bed. The two bags are continuous; the external bag forms the outer wall of the enclosure and the inner bag surrounds the mechanical portion of the bed, placing, in effect, only the mattress inside of the isolation enclosure. The console which forms the foot of the isolator contains the air filtration and supply system, pass-through locks for introduction of materials across the isolation barrier, and various ancillary controls for operation of the mechanical bed, the air supply system, and other equipment. The head contains storage areas and connections for various electrical devices.

Preliminary Studies

Before a patient was actually confined within the isolator, the reliabilities of the individual components involved in maintenance of the microbial integrity of the system were determined. In addition, several sanitizing and

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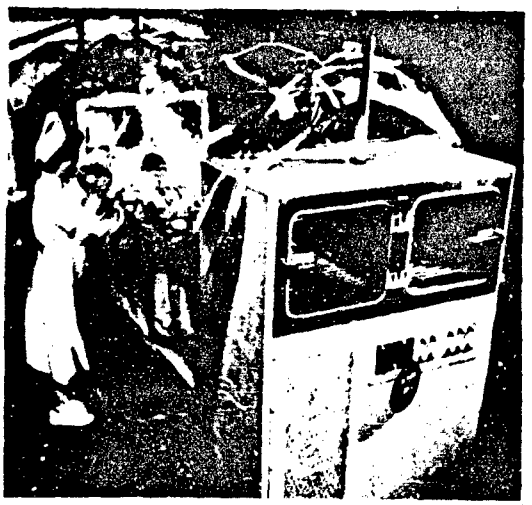

Fig. 1. The "Life Island" unitized patient isolator. The control console, foreground, houses the air filtration and supply system, ultraviolet irradiated pass-through locks (inlet shown) and various controls. The patient enclosure, formed of two over sized flexible polyvinylplastic bags, is fitted with rigid plastic view plates, gauntlet-gloves, and an overhead sliding suspension system. Only the mattress is contained within the actual enclosure. The mechanical portion of the bed together with electrical fittings controlling the elevation mechanism are contained within an inner plastic tunnel which is continuous with the exterior surface of the outer plastic bag. (U. S. Army photograph, Walter Reed Army Institute of Research.)

germicidal agents were evaluated for use in the occupied isolator.[3] The results of these preliminary studies may be briefly summarized here.

Air Filtration and Supply System

This system, which is designed to provide a continuous supply of bacteriologically sterile air to the interior of the isolator, is dependent upon ultra-high efficiency filter units (UHEF). The reliability of the system was measured in a series of experiments in which highly concentrated aerosols of a test organism, *Serratia marcescens*, were introduced at various points in the combined filtration and air supply system.

In two such experiments, aerosol clouds were introduced directly into the intake port of the filtration system. Blood agar plates were positioned at various points within the system and at the exhaust port of the filter units. The results of these experiments (Table I) clearly demonstrated that regardless of attempted overload or saturation of the filter units, there was no detectable penetration of the system by any of the challenges. This is seen in the results presented which show that while positive bacterial recoveries were obtained at sampling points located at the air intake of the system and between primary roughing filters and the UHEF units, those plates which were impinged upon directly by the efferent air stream of the filter units remained bacteriologically sterile.

TABLE I

EVALUATION OF THE ULTRA-HIGH EFFICIENCY FILTRATION (UHEF) UNITS BY CHALLENGE WITH AEROSOL SUSPENSIONS OF *Serratia Marcescens* (3)

Sampling Point	Sample Replicate	Experimental Series 1	2
		CFU* counts per exposed plate after 10 minutes exposure to air stream	
1. Efferent air stream from roughing filter	A	30**	>500
2. Efferent air stream from UHEF unit	A	0	0
	B	0	0
	C	0	0
3. Settling plates exposed at test site, external to UHEF system	A	43**	115**
	B	15**	120**

* CFU—Colony counts, scored as Colony Forming Units, recovered on blood agar plates following exposure and subsequent incubation at 25–27°C. for 48 hours.

**—Including mixtures of *S. marcescens* and various bacterial and mycotic components of the airborne microflora of the test site.

Germicidal Efficiency of the Ultraviolet Lamps

The pass-through locks of the isolator were each fitted with four ultraviolet germicidal lamps in order to provide for bacteriological decontamination of surfaces of objects being introduced across the isolation barrier. The lamps also provided for decontamination of the large volumes of air displaced during manipulation of the locks. The germicidal and sporocidal efficiencies of the lamps in sterilizing smooth surfaced materials monocontaminated with representative microorganisms including *Staphylococcus aureus, Streptococcus faecalis, Escherichia coli, Proteus vulgaris, Pseudomonas aeruginosa, Candida albicans* and *Bacillus subtilis* were determined.

Survival rates were obtained for each of the test organisms following graded periods of irradiation within the locks (Fig. 2). *P. vulgaris* and *Ps. aeruginosa* proved most susceptible; total sterilization was obtained within 30 seconds following introduction into the locks. *E. coli* and *S. aurus* were somewhat more resistant, requiring 60 to 90 seconds exposure for complete sterilization. *C. albicans* was found to be the most resistant of the test organisms other than *B. subtilis* with exposure in excess of two minutes being required for complete sterilization. Data obtained for *B. subtilis* indicated that while vegetative cells of sporogenic bacteria were rendered nonviable with less than two minutes of irradiation, complete sterilization including destruction of bacterial spores could not be achieved without irradiation for periods in excess of ten minutes.

From the above data, it was concluded that although the ultraviolet lights would provide effective bacterial decontamination of smooth-surfaced objects and of unobstructed air volumes, total surface sterilization could not be obtained without prolonged periods of expo-

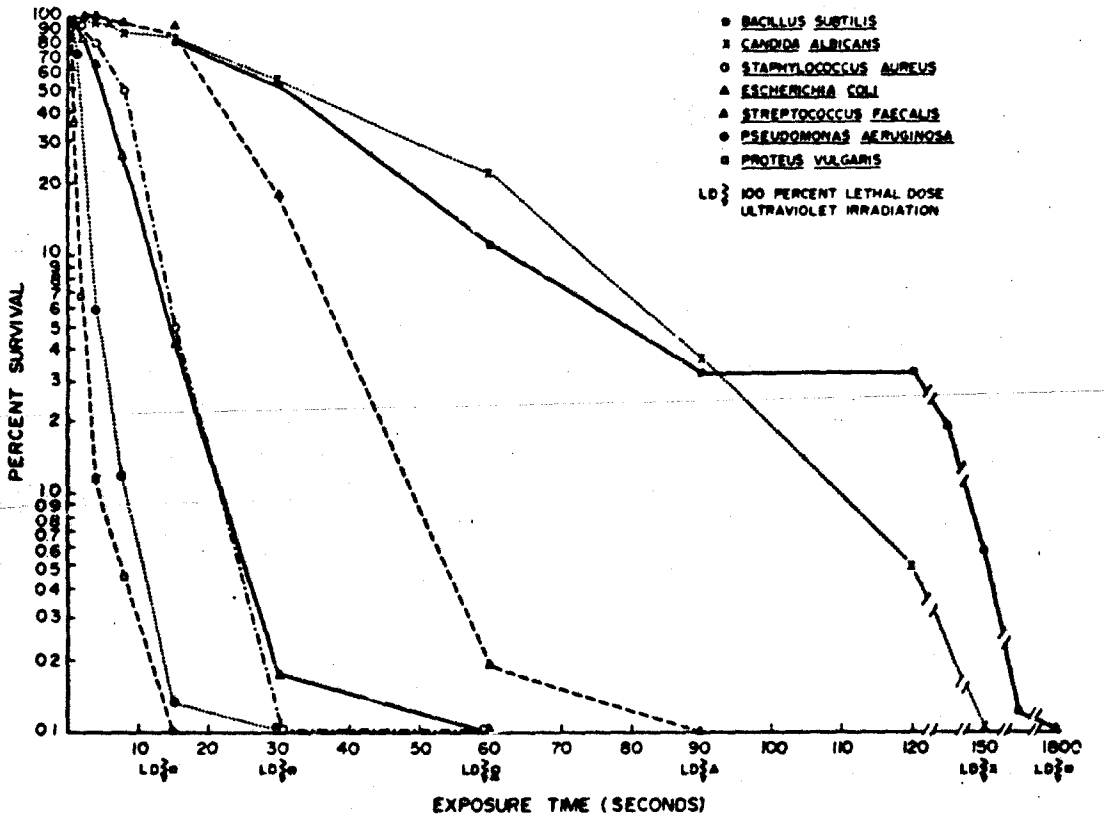

Fig. 2. Efficiency of sterilization by ultraviolet light in the irradiated pass-through locks as determined for several microbial species. Monocontaminated smooth surfaces were exposed at a distance of 12 inches from two G-8T5 germicidal lamps mounted in the ceiling of one lock.

sure. Accordingly, a minimum exposure period of no less than three minutes was recommended for routine surface decontamination of all presterile items being introduced through the locks into the isolator. An exposure period of 15 minutes was recommended for items being introduced as nonsterile, including presterilized items introduced in nonsterile outer wrappings.

Evaluation and Selection of Germicides

The selection of germicidal or sanitizing agents for use in concurrent sanitization of the occupied isolator was guided by three requirements including: (1) absence of toxic residual vapors; (2) freedom from any tendency to react either chemically or physically with the PVC material; and (3) possession of a high level of broad germicidal activity against a variety of representative microorganisms under limited conditions of application and exposure. The first two criteria eliminated many agents, particularly those belonging to the substituted or synthetic phenol and the iodiophoric classes. Those agents which were selected for final study, together with a summary of the results of the evaluations, are detailed in Table II.

Only two agents, benzalkonium chloride and a commercial product, Ves-phene, were found to be acceptable in terms of being nonreactive with the plastic material. Wescodyne was unacceptable because of a marked tendency to produce a permanent discoloration of the plastic. The remaining agents were considered unacceptable because of varying tendencies to leave residual films on the plastic.

In a comparison of the individual and overall efficiencies of the germicidal agents against a battery of various test organisms, Tergisyl, benzalkonium chloride, Amphyl, and Ves-phene proved to be the most effective. These results, together with those obtained for the chemical and physical compatibilities of the agents and the PVC material, indicated that only two agents were suitable for use in concurrent sanitization procedures. These were Ves-phene and benzalkonium chloride.

The findings from these preliminary studies demonstrated (1) that the isolator, together with its various components, is technically capable of providing a reliable means of patient isolation, and (2) that procedures are available for the effective sanitization of the isolator during prolonged periods of occupancy. These conclusions were further proven by actual clinical studies.

TABLE II

EVALUATION OF GERMICIDES FOR USE IN CONCURRENT SANITIZATION OF THE OCCUPIED PATIENT ISOLATOR

Germicide	Compatibility		Effective Surface Decontamination Ratings*							
	Chemical	Physical	*E. coli*	*P. vulgaris*	*Ps. aeruginosa*	*S. aureus*	*S. faecalis*	Grp. C Streptococci	*B. subtilis*	Overall Rating
Wescodyne	U	A	1	4	6	1	6	6	7	5
Tergisyl	A	U	3	1	7	3	2	2	1	2
Benzalkonium Chloride	A	A	2	3	3	2	3	1	4	1
Amphyl	U	A	4	2	4	5	4	3	3	4
SBT	U	U	6	5	2	7	5	7	5	6
SBT-24	A	U	7	6	5	6	7	5	6	7
Ves-phene	A	A	5	7	1	4	1	4	2	3
Saline Control	A	A	–	–	–	–	–	–	–	–

U—Unacceptable.

A—Acceptable.

* Ranked according to a comparison of the individual efficiencies of the different germicidal agents in sanitizing monocontaminated strips of polyvinylchloride plastic (3).

Clinical Studies

Detailed data on the behavior of patient microflora and the development of bacterial contamination within the isolator during prolonged periods of occupancy were obtained in two clinical trials of the isolator. In one study, an adult volunteer remained within the isolator for a period of 12 days. In the second study, a child with the diagnosis of aplastic anemia was confined for nine days with one interruption when he was removed for surgery. With this patient, the heroic efforts of isolator confinement were not a successful life-saving measure.

Prior to their introduction into the isolator, both patients were bathed and shampooed with a commercial lotion containing three per cent hexachlorophene. Partial and complete baths were routinely given to both patients during their periods of confinement. Antimicrobial therapy for the child included Staphcillin® (8 grams, i.d.), Keflin® (500 mg. i.d.), and tetracycline (250 mg., q.i.d.). No antimicrobial therapy was prescribed for the adult.

Substantial evidence of the reliability of the isolator was obtained during the first study employing the adult volunteer. Detailed daily bacteriological examination of the external and intestinal microflora of the volunteer gave no evidence of colonization by any exogenous microorganisms during his confinement within the isolator.[4] These examinations also revealed that the volunteer was an intestinal carrier of both *S. aureus* and a readily recognizable strain of *S. epidermidis* as well as respiratory carrier for a type III strain of *Klebsiella pneumoniae*.

Examination of the levels of microbial contamination within the occupied isolator gave both further evidence of the reliability of the system and data regarding the effectiveness of sanitization procedures.[5] A total of 165 samples were collected from various surfaces or fomites within the isolator during the period it was occupied by the adult volunteer (Table III). Of these, 118, or 71.5 per cent, were bacteriologically negative on culture. Of the samples obtained from the different fomites, 34 per cent yielded positive cultures. Microorganisms isolated from these cultures included *S. epidermidis, S. aureus, K. pneumoniae, E. coli* and *S. faecalis*. All of these were determined to be identical to corresponding isolates recovered during the same period directly

TABLE III

DISTRIBUTION OF MICROBIAL CONTAMINATION WITHIN THE OCCUPIED PATIENT ISOLATOR
(12 days of reverse isolation, adult volunteer)

Specimen Source	Positive Recovery Rate	Bacteriological Identifications		
		Identification	Number of Isolations	Probable Source
Fomites	23/68	*S. epidermidis*	14	Patient*
		Klebsiella-aerobacter	5	Patient
		S. aureus	4	Patient
		E. coli, S. faecalis, Cloistridium sp.	1 ea.	Patient
Interior Surfaces	27/97	*S. epidermidis*	18	Patient
		S. aureus	8	Patient
		Klebsiella-aerobacter	3	Patient
		Bacillus sp.	2	UNKNOWN
		S. faecalis	2	Patient
		ahem9. Streptococci	1	Patient

* Justified on basis of biochemical, cultural or serological similarities with isolates recovered directly from patient (5).

TABLE IV

COMPOSITION OF RECOVERABLE PATIENT MICROFLORA
(9 days of reverse isolation; 11 yr. m., aplastic anemia)

Specimen Source	Positive Recovery Rate	Bacteriological Composition	
		Identification	Number of Isolations
Skin Surfaces	20/34	*C. albicans*	14
		S. epidermidis	6
		Kebsiella-aerobacter	2
		Pityrosporum sp.	2
Body Orifices:			
Oral	9/9	*C. albicans*	9
		Klebsiella-aerobacter	9
		Grp. D. Streptococci	5
		α hemo. Streptococci	2
		S. epidermidis	1
Nasopharyngeal	3/4	Klebsiella-aerobacter	4
		C. albicans	2
		S. epidermidis	2
Rectal	7/7	Klebsiella-aerobacter	7
		C. albicans	6
		Grp. D. Streptococci	5
		E. coli	5
		Alkaligenes-dispar	1
		α hemo. Streptococci	1
		P. vulgaris	1

from the patient and thus attributed to contamination of patient origin.

Examination of the positive cultures obtained from samples taken from various surface areas within the isolator yielded similar results (Table III). The positive culture recovery rate for these specimens was 25 per cent; identifications included *S. epidermidis*, Klebsiella—aerobacter, *S. faecalis* and alpha hemolytic streptococci. With the exception of a strain of an aerobic sporogenic bacillus which was recovered from two specimens, all of the surface contaminants could be equated with similar organisms harbored by the patient. As before, no transmigration of microorganisms indigenous to the external hospital microflora or attendants was detected.

In spite of the death of the child in the second application of the isolation system, enough bacteriological data were obtained during his nine days of confinement to give further evidence of the reliability of the equipment (Table IV). Prior to isolation, the child had suffered several episodes of bacteremia due to *S. aureus* and *K. pneumoniae*. In addition, *C. albicans* was recovered repeatedly from both stool and upper respiratory tract specimens. Bacteriological monitoring of the child included examination of 34 specimens taken from several skin surfaces and 21 specimens obtained from various body orifices. Twenty, or 59 percent, of the skin surface cultures were bacteriologically positive; the predominant isolates included *C. albicans*, *S. epidermidis*, and *K. pneumoniae*. All of the body orifice specimens yielded positive cultures although growth was uniformly sparse. The predominant isolates, again, were *C. albicans*, *S. epidermidis* and *K. pneumoniae*. In total, 41 of 55 specimens obtained from the child were

bacteriologically positive. *C. albicans*, as the predominant isolate, was recovered from 31 separate specimens, *K. pneumoniae* was recovered 22 times and *S. epidermidis* recovered nine times. Other frequently isolated microorganisms included group D streptococci and enterococci, *E. coli*, and alpha hemolytic streptococci.

Because of the child's critical condition, bacteriological monitoring of surfaces and fomites within the interior of the isolator during his confinement was limited; however, 54 specimens were collected over the nine-day period. Of these, nine, or 17 per cent, were bacteriologically positive on culture (Table V). Only three species were recovered from the positive cultures; these included seven isolations of *C. albicans* and one isolate each of *S. epidermidis* and *K. pneumoniae*. All three microorganisms were found to be identical with strains recovered from the patient in all properties tested. In spite of the one interruption in isolation and several potential compromises in technique, no contamination of external origin was detected either within the isolator or in specimens obtained from the child.

Quantitative and qualitative examination of the levels of airborne microbial contamination within the occupied isolator provided further evidence of the integrity of the reverse isolation barrier.[5] This is particularly true of data obtained druing the second study during which air samplings were conducted daily from the second to eighth day (Table VI). Paired slit samplers were used to permit simultaneous sampling of equal volumes of air both inside and outside of the occupied isolator. The internal levels of airborne contamination routinely averaged less than seven per cent of the corresponding external values with several negative samples being recorded. It is of major significance that only two species, *S. epidermidis* and *C. albicans*, were recovered from the internal air volumes; these organisms, again, were identical to corresponding strains recovered from the patient. The external aeromicroflora were found to be comprised of numerous bacterial and fungal forms including several pathogenic species.

The results obtained from these latter studies are also pertinent in an examination of problems which might be associated with care of patients confined within the isolator. As noted in Table VI, *C. albicans* was recovered on several occasions from the external air volume samples in the immediate area of the isolator. Procedures which would have established the degree of identity between these recoveries and similar recoveries from within the isolator were not available. Accordingly, the relationship between contamination of the interior of the isolator by this organism and its subsequent detection as an external airborne contaminant cannot be determined. However, it is significant that no measures were taken to provide for decontamination or filtration of air exhausted from the unit. Thus, these findings suggest that further consideration of the problems associated with control of contamination arising within the isolator and

TABLE V

DISTRIBUTION OF MICROBIAL CONTAMINATION WITHIN THE OCCUPIED PATIENT ISOLATOR
(9 days of reverse isolation; 11 yr. m., aplastic anemia)

Specimen Source	Positive Recovery Rate	Bacteriological Identifications		
		Identification	Number of Isolations	Probable Source
Fomites	4/20	*C. albicans*	4	Patient*
Interior Surfaces	5/34	*C. albicans*	3	Patient
		K. pneumoniae	1	Patient
		S. epidermidis	1	Patient

* Justified on basis of biochemical, cultural or serological similarities with isolator recovered directly from patient.

TABLE VI

LEVELS AND COMPOSITION OF AEROMICROFLORA WITHIN AND EXTERNAL TO THE OCCUPIED PATIENT ISOLATOR
(9 days of reverse isolation; 11 yr. m., aplastic anemia)

Day of Isolation	Isolator Interior		Exterior Area	
	Count*	Identifications	Count*	Identification
2, 1000 hrs.	3	*S epidermidis*	140	*S. aureus* *Neisseria sp.*
3, 0800 hrs.	7	*S. epidermidis*	93	*S. epidermidis* *S. aureus* *Neisseria sp.*
3, 2000 hrs.	0	- - - - -	80	*S. epidermidis*
4, 1000 hrs.	7	*S. epidermidis*	87	*S. epidermidis* *Neisseria sp.*
5, 0900 hrs.	10	*S. epidermidis*	203	*S. epidermidis* *S. aureus* *Neisseria sp.*
6, 0830 hrs.	13	*C. albicans* *S. epidermidis*	50	*S. epidermidis* *S. aureus* *Neisseria sp.* *Bacillus sp.*
7, 0830 hrs.	0	- - - - -	43	*S. aureus* *S. epidermidis* *C. albicans*
8, 2200 hrs.	3	*C. albicans* *S. epidermidis*	133	*S. epidermidis* *C. albicans* *Bacillus sp.*

* Bacterial counts corrected to values per 1,000 cu. ft. Identifications include all isolates recovered from interior sampling plates and the predominant isolates recovered from the exterior sampling plates.

transmigrating outwards is required. This does not, however, detract from the demonstrated reliability of the isolator in providing an effective form of reverse isolation for the infection-prone patient.

Summary

The microbial reliability of a unitized patient isolator has been examined in a series of preclinical evaluations and clinical studies. The results may be summarized as follows: The different subsystems and components upon which the isolator is dependent were demonstrated to be technically capable of providing and maintaining a microbiologically reliable isolation barrier. Evaluation of various germicides resulted in selection of several agents suitable for use within the occupied isolator and thus insured a means of sanitization of the unit over prolonged periods of occupancy. These studies demonstrated the potential value of the isolator in providing a means of sequestering or isolating the highly susceptible patient from contact with potentially pathogenic components of the hospital environment microflora. The reliability of the system in providing a means of complete reverse isolation has been proven in actual clinical situations in which patients have been maintained in the isolator for as long as 12 days without detectable microbial penetration of the isolation barrier.

REFERENCES

[1] Ginsberg, M. L. and La Conte, M. L.: Reverse isolation. Am. J. Nurs., 64:88, 1964.

[2] Glor, B. A. K., Ginsberg, M. K., Shadomy, S., and Nichols, G. A.: The RES system; a new concept of reverse isolation. Mil. Med. (in press), 1966.

[3] Shadomy, S., Ginsberg, M. K., La Conte, M. L., and Zeiger, E.: Evaluation of a patient isolator system: I. Evaluations of sub-systems and procedures for sterilization and concurrent sanitization. Arch. Environ. Health, 11:183-90, 1965.

[4] Shadomy, S., Ginsberg, M. K., and Zeiger, E.: Evaluation studies of a patient isolator system: II. Distribution profiles of patient microflora during prolonged isolator confinement. Arch. Environ Health, 11:191-200, 1965.

[5] Shadomy, S., Ginsberg, M. K., and Zeiger, E.: Evaluations of patient isolator system: III. Microbial contamination of the isolator interior. Arch. Environ. Health, 11:652-61, 1965.

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